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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,937	05/28/2002	Brent C. Gerberding	S63.2-10447	2387
490	7590	08/11/2005		
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185				
			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/063,937	<b>Applicant(s)</b> GERBERDING, BRENT C.	
	<b>Examiner</b> Elizabeth Houston	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13-18,22-28 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-10,13-18,22-28 and 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/26/05 has been entered.

### ***Drawings***

2. The drawings were received on 07/26/05. These drawings are acceptable.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 36 claims a stent with serpentine patterns of

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struts, a different pattern of struts in the central region, with regions of enhanced radiopacity *located on struts* between areas of un-enhanced radiopacity. The only figure that this claim can be directed toward is Figure 1f as by the designation of a *different pattern of struts in the central region*. However, in this figure, the region of enhanced radiopacity is not *located on struts with serpentine patterns*. There is no further explanation in the specification.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by Jang (USPN 6,241,760).

7. Jang discloses a stent (Fig. 7A) comprising a first end region and a second end region and a central region. The pattern of struts in the central region (only expansion columns 24) differs from the patterns of struts in the first and second regions (expansion columns 24 and reinforcement expansion columns 86) (Col 10, line 2). Jang states that the stent are typically partially plated with radiopaque material by plating both ends from

1 to 3 or more expansion columns. In that respect the ends could be coated up to 6 expansion columns thereby delineating the central region of the stent.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-2, 4-5, 7, 9-10, 13-18, 23-24, 26-28, 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (USPN 6,730,116) in view of Erbel et al. (USPN 2004/0116998).

10. Wolinsky teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands formed of interconnected struts (Figs. 1-14), special struts (Fig. 3, 28 and Fig. 8, 62a) with enlarged width that extends between peaks and troughs, having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 6, line 67) between the two regions. There are a plurality of struts on either side of the special strut have a curvature that curves about the special strut (Figs 3 and 8). The special struts are in a region between the ends of the stent. One of the special struts is located in a serpentine band at one end and the other special strut is located in a serpentine

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band at another end of the stent. Wolinsky further teaches, "stents can be used to repair aneurysms" (Col. 1, line 36). Wolinsky fails to teach a stent with a cover.

11. Erbel discloses an endovascular prosthesis (Fig. 3) or stent comprising an annular portion with a porous section (20) and a nonporous section (25). As to claims 4-5, and 34-35, the nonporous section (25) or cover is disposed about the circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para70-72). As to claim 7 Erbel discloses a cover disposed about the stent in a region including radiopaque markers (35). The radiopaque markers designate the proximal and distal ends of the region of the cover. Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).

12. It would have been obvious to one of ordinary skill in the art to incorporate a cover onto the stent to enhance the capabilities of the stent. Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it could then be used to treat aneurysms and tears. He further provides the motivation for using radiopaque markers at the end regions of the cover. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

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13. As to claims 26 –28, the special struts are designated as the struts that are defining the periphery of the cover. In this case, the radiopaque struts outlining the cover are “special” over any other radiopaque strut or non-radiopaque strut because they serve the “special” purpose of defining the cover.

14. As to Claims 13 and 14, they are rejected to as Product by Process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). (See MPEP § 2113) As stated above, the product is clearly anticipated by Wolinsky in view of Erbel and so claims 13 and 14 are unpatentable even though the prior art was made by a different process.

15. Claims 8 and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Erbel.

16. Wolinsky in view of Erbel discloses a stent with special struts and a cover as stated above. Wolinsky in view of Erbel teaches that using radiopaque markers to designate the proximal and distal ends of the region of the cover facilitates correct placement of the stent.

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17. Wolinsky in view of Erbel does not disclose the size of the cover and therefore does not disclose that the special struts are located anywhere between the middle of the stent and a position one half of the way from the middle of the stent to an end of the stent.

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to alter the size of the cover depending on size of the vessel, the size of the stent and the size of the lesion that it is treating. And therefore the markers could be located at a position one half of the way from the middle of the stent to an end of the stent.

19. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

20. Wolinsky in view of Erbel teaches a stent with a cover marked at the periphery by special radiopaque struts. Wolinsky in view of Erbel does not teach a second cover.

21. Barone teaches a stent with two covers shown in Fig. 7. The figure shows two stent grafts occluding where the vessel is ruptured but keeping the flow of the blood through the ostium of the vessel branch. Barone states that the use of 2 covers is desirable to repair blood vessels with lesions wherein the wall of the vessel is not in condition to receive and firmly retain an implanted graft (Col 2, lines 20-25 and Col 1, lines 8-17).



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22. At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the second cover of Barone into the stent of Wolinsky in view of Erbel. Barone provides the motivation in that a stent with two covers enhances the function of the stent since it can be used to repair branched vessels with multiple lesions. The inventions are analogous with each other and the instant invention and so the combination is proper.

23. Claim 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view Erbel as applied to claim 16 above and further in view of Thornton et. al (USPN 6,551,350).

24. Wolinsky in view of Erbel meets the claim limitations as stated above but fails to disclose a stent in bifurcated form.

25. Thornton teaches a stent in bifurcated form as shown in Fig. 15. Thornton further teaches that a bifurcated stent is necessary when a defect, such as an aneurysm, is located very close to the bifurcation of a trunk lumen into branch lumens. Without a bifurcated stent, treatment becomes difficult because neither the trunk lumen nor the branch lumens provides a sufficient portion of healthy lumen wall on both sides of a defect to which a straight single lumen stent can be secured (Col. 1, paragraphs 6-8).

26. It would have been obvious to one skilled in the ordinary art at the time of the invention to design a radiopaque stent in bifurcated form. Thornton provides the motivation for the combination in that it is necessary to treat aneurysms and defects

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located close to the bifurcation of a trunk lumen into branch lumens. The inventions are analogous with each other and the instant invention, and so the combination is proper.

### ***Response to Amendment***

27. The amendment filed 07/26/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 36 claims a stent with serpentine patterns of struts, a different pattern of struts in the central region, with regions of enhanced radiopacity *located on struts* between areas of unenhanced radiopacity. The only figure that this claim can be directed toward is Figure 1f as by the designation of *a different pattern of struts in the central region*. However, in this figure, the region of enhanced radiopacity is not *located on struts with serpentine patterns*.

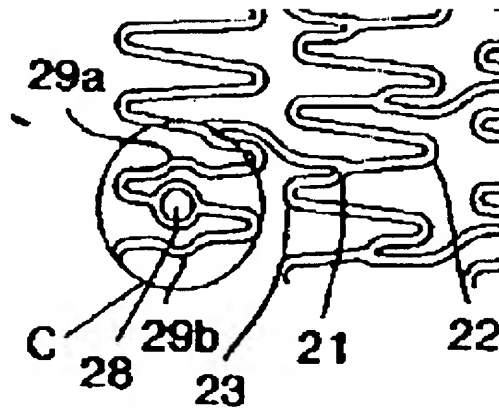
Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Response to Arguments***

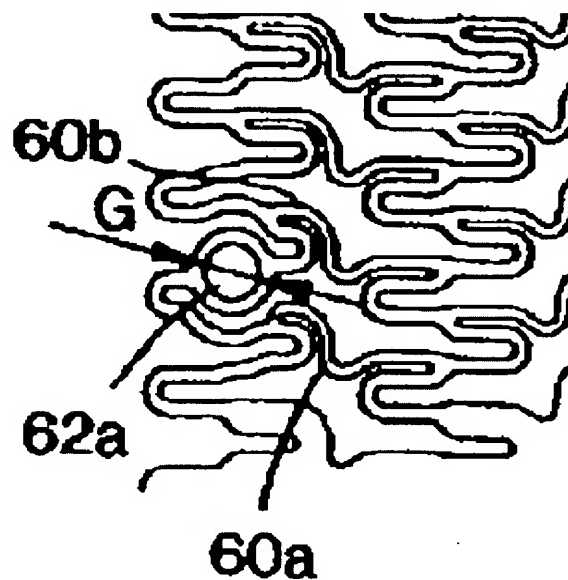
28. Applicant's arguments, see pages 9-13, sections 2, 3, 10-16 and 17-20 filed 07/26/05, with respect to the rejections of claims 16 and 17 under Cox; of claim 25 under Cox in view of Thornton; of claims 1-2, 4-5, 7-10, 15-18 and 34-35 under Cox in view of Erbel; and of claim 6 under Cox in view of Erbel further in view of Barone have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of a previously applied reference.

29. Applicant's arguments filed 07/26/05 have been fully considered but they are not persuasive. In respect to the prior art of Wolinsky, Applicant has states that Wolinsky does not suggest the recited plurality of interconnected struts adjacent the first side which have curved regions which curve about the first region of the special strut or a plurality of interconnected struts adjacent the second side which have curved regions which curve about the second regions of the special strut. Examiner directs applicant attention to figures 3 and 8. In figure 3, it is clear that there is at least a plurality of interconnected struts adjacent the first side which have curved regions which curve about the first region of the special strut (referring to 29a and strut directly above). This figure however does not show a second strut on a second side, though it is inherent that the second adjacent strut on the second side would be curved just as the second adjacent strut on the first side is. Furthermore figure 8 shows that the second adjacent struts have a bit of curvature compared to the remaining struts that are not surrounding the special strut. Therefore the rejection of Wolinsky remains as stated above.



**FIG. 3**



**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-

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7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh



  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

8/2/05